



Chugai, SoftBank Corp., and SB Intuitions Sign Memorandum of Understanding for Joint Research Aimed at Innovating Clinical Development Processes and Accelerating New Drug Development through Generative AI - Aiming to Create Advanced Services in the Pharmaceutical and Healthcare Industry -

- Initiating cross-industry collaboration to improve efficiency and productivity in clinical development processes through the use of generative AI
- Developing AI agents to support clinical development personnel, aiming to accelerate new drug development
- Ultimately aiming to deliver new drugs more quickly to patients eagerly awaiting them through broader industry application in the future

TOKYO, January 30, 2025 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519, hereafter "Chugai"), [SoftBank Corp.](#) (TOKYO: 9434, hereafter "SoftBank"), and its subsidiary [SB Intuitions Corp.](#) (Japanese-only website, hereafter "SB Intuitions") announced today that they have signed a Memorandum of Understanding, effective January 30, 2025, to conduct joint research aimed at innovating clinical development processes¹ in new drug development using generative AI (Artificial Intelligence) (hereafter "this initiative"). The three companies aim to significantly improve the productivity of clinical development processes and accelerate new drug development.

In the current drug development process, it takes approximately 9 to 17 years² for a single pharmaceutical product to reach the market, requiring substantial investments ranging from tens to hundreds of billions of yen², including costs associated with failures. Among the various stages of drug development, clinical development processes have the most significant impact in terms of both cost and duration. The application of generative AI in this area is expected to greatly enhance efficiency and productivity.

As a first step, the three companies will jointly develop AI agents capable of autonomously executing clinical development tasks, along with a large language model (LLM) specifically tailored to the pharmaceutical industry to maximize these agents' capabilities. By leveraging generative AI based on this LLM, the three companies aim to significantly streamline the personnel and costs associated with clinical trials.

The implementation of generative AI into our operations will be conducted in phases. Initially, the three companies will develop prototype AI agents for specific tasks such as automatically generating numerous documents required for clinical trials, collecting essential information on diseases, industry regulations, and internal procedures, and performing exploratory data analysis³. Subsequently, they will expand the scope of tasks to cover the entire clinical development process, evolving into a multi-agent system where multiple AI agents collaborate. By having this multi-agent system work in conjunction with human operators, we expect to streamline various tasks in clinical development. This is anticipated to reduce the time required for conducting individual clinical trials and submitting new drug applications, as well as decreasing personnel requirements and costs, making it possible to allocate resources to a greater number of new drug development projects.

Through this initiative, the three companies aim to accelerate new drug development and deliver innovative treatments to patients more rapidly. Furthermore, they expect that this effort will contribute to strengthening the international competitiveness of Japan's healthcare industry.

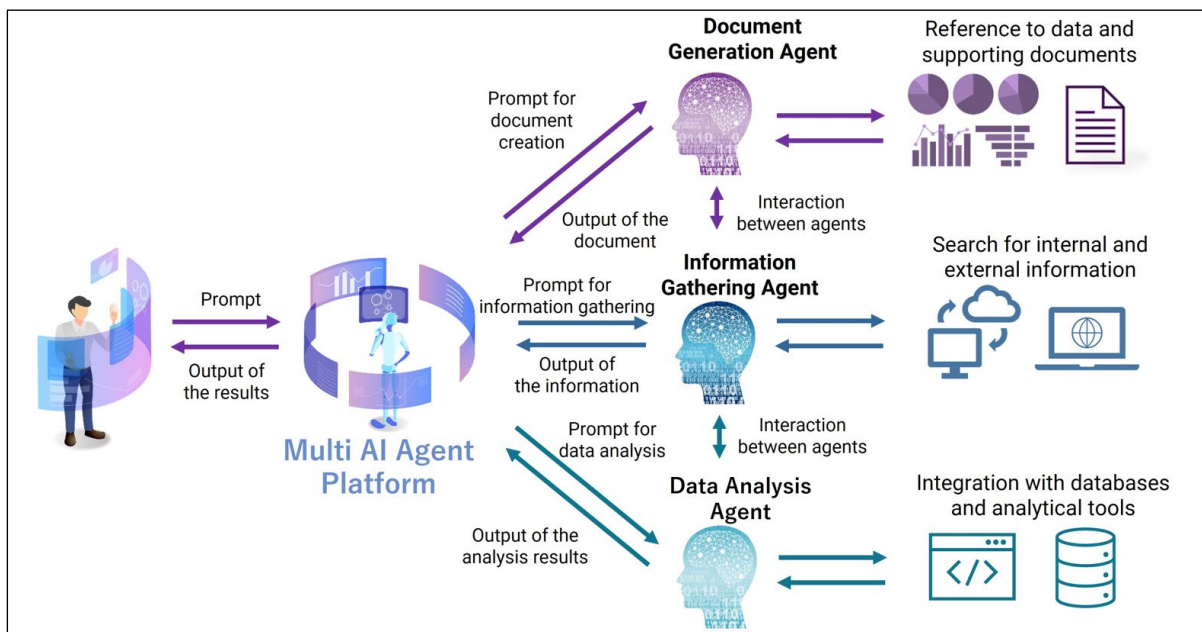
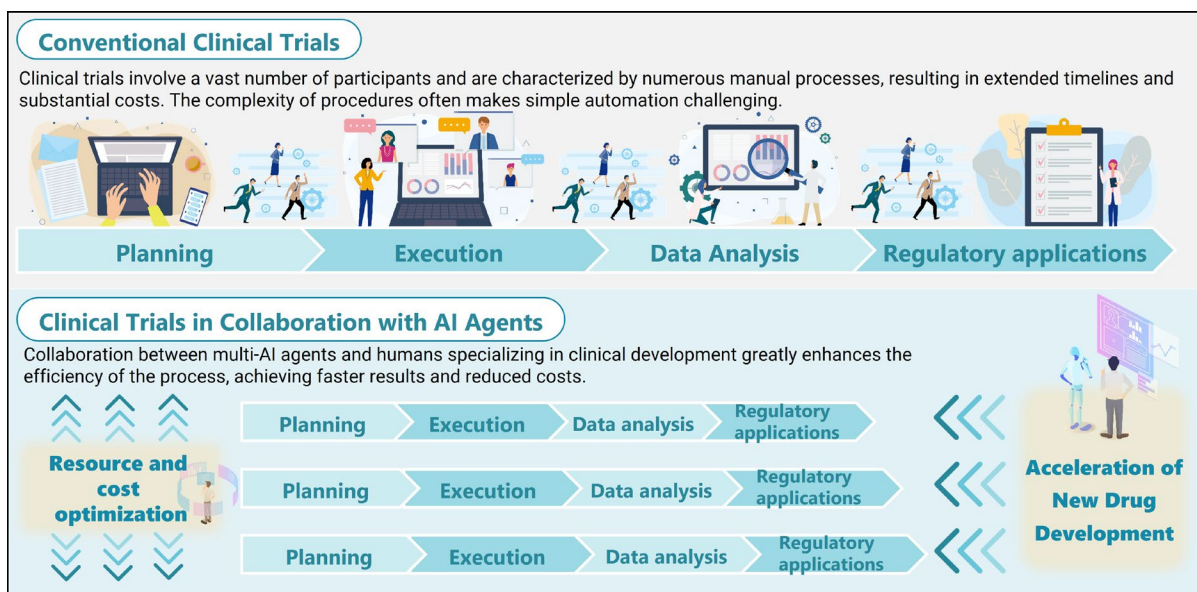


Image of AI Agents



Expected Effects of Utilizing AI Agents in Clinical Development Operations

Comments from Each Company:

"To deliver innovative medicines to patients as quickly as possible, reducing the time and cost required for clinical development is a crucial challenge. As a company boasting one of the largest pipelines in Japan, we aim to optimize resources and costs, and accelerate drug development through collaboration between clinical development experts and AI. By reconstructing our business processes with digital technology at the core and dramatically improving productivity, we will realize the 'creation of an advanced business model' as outlined in our growth strategy TOP I 2030," said Dr. Hitoshi Iikura, Chugai's Director and Executive Vice President.

"The implementation of AI agents utilizing generative AI is expected to have a significant impact on shortening and streamlining clinical development processes. Through this collaboration, we will establish a foundation for effectively utilizing generative AI. Simultaneously, we aim to create innovative services in the pharmaceutical and healthcare industries while engaging new partners both within and outside the industry," said Takao Suzuki, Chugai's Associate Vice President and Digital Transformation Unit.

"We expect that the realization of an LLM specialized for clinical development, powered by one of Japan's largest AI computational infrastructures, will lead to more efficient development processes. SoftBank, while continuing to build next-generation social infrastructure, will also address various social issues as an 'AI Transformation

Integrator' promoting corporate transformation through AI," said Hayato Sakurai, SoftBank Corp.'s Executive Vice President and Head of Enterprise Unit.

"We believe that this partnership with Chugai will not only dramatically revitalize the field of clinical development but also represent a significant step forward for the entire healthcare industry in Japan. The development of AI agents for clinical development tasks will challenge past conventions and serve as a catalyst for numerous new initiatives aimed at solving societal issues. AI is not merely a tool, but a core engine of the next-generation digital social infrastructure. At SB Intuitions, we aim to enrich Japanese life through digital services and will continue to strive for the development of safe and accurate AI services," said Hironobu Tamba, SB Intuitions' President & CEO.

These three companies will deepen their partnership beyond industry boundaries and work on solving challenges, taking this initiative as an opportunity. In the future, we aim to deliver new drugs to patients as quickly as possible through social implementation for wider industry adoption.

Roles of Each Company:

Chugai

- Provision of training data for the clinical development-specialized LLM
- Planning and evaluation of AI agents for clinical development operations

SoftBank Corp.

- Provision of AI computing infrastructure
- Promotion of social implementation of the clinical development-specialized LLM and AI agents

SB Intuitions

- Research and development of the clinical development-specialized LLM
- Research and development of AI agents for clinical development

Chugai Pharmaceutical Co., Ltd.

Chugai Pharmaceutical Co., Ltd., headquartered in Tokyo, is a research-based pharmaceutical company with world-class drug discovery capabilities, including proprietary antibody engineering technologies. Chugai is committed to creating innovative pharmaceutical products that may satisfy unmet medical needs. Chugai is listed on the Prime Market of the Tokyo Stock Exchange. While maintaining autonomy

and management independence, Chugai is an important member of the Roche Group. Additional information is available at <https://www.chugai-pharm.co.jp/english/>

SoftBank Corp.

Guided by the SoftBank Group's corporate philosophy, "Information Revolution – Happiness for everyone," SoftBank Corp. (TOKYO: 9434) operates telecommunications and IT businesses in Japan and globally. Building on its strong business foundation, SoftBank Corp. is expanding into non-telecom fields in line with its "Beyond Carrier" growth strategy while further growing its telecom business by harnessing the power of 5G/6G, IoT, Digital Twin and Non-Terrestrial Network (NTN) solutions, including High Altitude Platform Station (HAPS)-based stratospheric telecommunications. While constructing AI data centers and developing homegrown LLMs specialized for the Japanese language with 1 trillion parameters, SoftBank is integrating AI with radio access networks (AI-RAN) with the aim of becoming a provider of next-generation social infrastructure. To learn more, please visit <https://www.softbank.jp/en/>

SB Intuitions Corp.

We are dedicated to researching Japanese-specific large language models and developing related services, aiming to achieve the top performance in Japanese language capabilities with our domestically produced large language model. Our model strives to truly reflect Japanese culture and values, and to provide services tailored to Japanese business practices. We continue our daily research efforts to ensure that our technology and services can contribute to the daily lives and businesses of a wide range of customers.

References:

1. Clinical Development Processes: This involves planning development strategies and clinical trial protocols for potential new drug candidates aimed at regulatory approval. It ensures that clinical trials are conducted, recorded, and reported appropriately according to plans and relevant regulations. It also includes monitoring and management to protect the rights, safety, and welfare of trial participants. Based on data obtained from clinical trials, summary reports and approval application documents are prepared, ultimately leading to the submission of a marketing authorization application to the Ministry of Health, Labour and Welfare's review agency.

2. Source: Ministry of Health, Labour and Welfare, "Current Status of the Pharmaceutical Industry" [Internet; cited January 2025].

<https://www.mhlw.go.jp/content/10807000/001036959.pdf> (Japanese only)

3. Exploratory Data Analysis: Additional analyses conducted separately from pre-specified analyses in the trial protocol, aimed at detecting safety signals in subjects or confirming the appropriate conduct of the trial.

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